Remarks

Applicants appreciate the comments provided in the office action mailed December 17, 2003. Applicants respectfully submit that the Amendment presented herein is fully responsive the office action and request that the Amendment be entered and the application reconsidered in view thereof. Claims 15-22 have been canceled without prejudice to the presentation of same in a divisional application in view of the election made by Applicants without traverse.

Applicants note the Information Disclosure Statement filed May 22, 2003 and the Supplemental Information Disclosure Statement filed on November 18, 2003. Applicants respectfully request acknowledgement by the Examiner that references cited therein have been considered.

Claims 1, 3 and 13 are objected to for the informalities noted in the Office Action. Applicants have amended the claims to clarify the relationship between the foam tissue scaffold component and the fixation component. The tissue scaffold component comprises a foam. The fixation component for fixing the implant in the body includes a support means for supporting the tissue scaffold component and an anchor means for anchoring the implant in the body. Initially, Applicants respectfully note that the amendment to claim 1 incorporates elements of original claim 2 into claim 1 and thus technically are not newly presented limitations. In any event, support for the support means and anchor means in relationship to the foam tissue scaffold component may be found in Figures 1-3a and in the specification at page 7, line 27 – page 8, line 29, as well as elsewhere in the specification. Applicants respectfully submit that the Amendment renders moot the objections to the claims.

Claims 7-10 are rejected under 35 U.S.C. 112, second paragraph, in that claim 7 recites "the bioabsorbable polymer" without clarification as to whether the reference is made to the foam tissue scaffold component or the fixation component. Applicants have amended claim 7 to clarify that the bioabsorbable polymer relates to the foam tissue scaffold component. Applicants respectfully submit that claims 7-10 are patentable under 35 U.S.C. 112, second paragraph and respectfully request that the rejection thereof be withdrawn.

Claims 1-5, 7-11, 13 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Gresser et al. Applicants respectfully traverse.

Gresser discloses an interbody spinal fusion device for use as spacers in spinal fixation (pp 8). The device may comprise a plurality of peripheral voids, or a central void space, which may be filled with a grafting material for facilitating bony development and/or spinal fusion, as well as resorption of the device by the body (pp). In particular, periosteum cells may be incorporated into a foam and placed into the voids (pp14). As shown in figures 1A through 5B, the device may be of various geometrical configurations. In particular, Figures 4A and 4B depict a device in the shape of a threaded screw. Cylindrical holes 43 and 44 are provided through the body of the device orthogonal to each other and to the screw axis, although the purpose for such holes is not disclosed. A cylindrical hole 45 is provided coaxially with the axis. Again, the purpose of the hole is not disclosed. Slots 46 and 48 serve to position and retain a tool for screwing the device into place.

Applicants respectfully submit that the main body of the device does not comprise foam, according to the specification, and thus cannot provide a foam tissue scaffold component. Nor is the fixation component, i.e. threads, partially encapsulated by a foam tissue scaffold component. Rather, the threads form a part of the spacer device. Applicants respectfully submit that Gresser fails to disclose or suggest a tissue scaffold implant device comprising a foam tissue scaffold component and a fixation component partially encapsulated by the tissue scaffold component, whereby the scaffold is fixedly attached to the fixation component. Accordingly, Applicants respectfully request that the rejection of claims 1, 3 and 13 over Gresser be withdrawn.

Claims 1-14 are rejected under 35 U.S.C. 102(e) as being anticipated by Melican et al. US 2002/0120348. In view of the Amendment Applicants respectfully traverse.

Applicants respectfully submit that Melican fails to disclose or suggest a tissue scaffold implant comprising a foam tissue scaffold component and a fixation component, where the fixation component comprises both a tissue scaffold support means and anchor means. While Melican does disclose that fixation devices, e.g. sutures or staples, may be employed with reinforced tissue implants disclose therein, Applicants respectfully submit that such devices do not include a tissue scaffold support and anchor means.

Accordingly, Applicants respectfully submit that Melican fails to anticipate any of claims 1-14 and respectfully request that the rejection jnder 35 U.S.C. 102(e) be withdrawn.

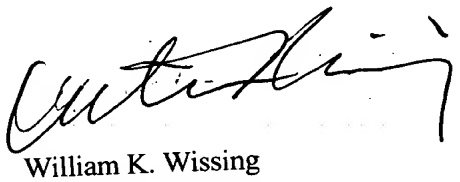
Claims 1-14 are rejected under 35 U.S.C. 1-2(e) as being anticipated by Sherwood et al., US 6,454,811. Applicants respectfully traverse.

Sherwood discloses composites for tissue regeneration made by using solid free form processes. Materials used to prepare the Sherwood devices must be amenable to milling and sieving to produce specific particle size powders. (Col. 8, ll. 3-5). As such, Sherwood utilizes powders to form composites disclosed therein, not foam. In fact, Sherwood is void of any reference to foam or devices made from foam. Accordingly, Applicants respectfully submit that claims 1-14 are not anticipated by Sherwood and

respectfully request that the rejection of claims 1-14 under 35 U.S.C. 102 (e) be withdrawn.

Based on all of the foregoing, Applicants respectfully submit that claims 1-14 are patentable and earnestly request a Notice of Allowance to that affect.

Respectfully submitted



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